

REMARKS

Claims 24-26, 29, 31, 34-35, 48-49, and 52-53 are pending in this application. Claims 24, 31, and 49 have been amended as discussed herein. Claims 27-28, 30, 32, 33, 36-47, and 50 have been canceled without prejudice or disclaimer. No new matter has been added. The Office Action is discussed below.

Priority and Sequence Compliance Issues Resolved:

In view of the response filed on October 14, 2010, the examiner has agreed that the foreign priority based on an application filed in Australia on 4-8-2004 is deemed to be perfected and the application now complies with the sequence listing requirements of 37 C.F.R. 1.821-1.825. Applicants thank the examiner for the consideration.

Withdrawal of Enablement, Written Description, Indefiniteness, and Anticipation Rejections:

On pages 2-3 of the Office Action, in view of the response and amendment filed on October 14, 2010, the examiner has withdrawn the rejections of claims 24-35 under 35 U.S.C. 112, first and second paragraphs. The examiner also has withdrawn the rejection of claims 24-35 under 35 U.S.C. 102(a) alleged as being anticipated by Whilley *et al.* Applicants thank the examiner for the withdrawals.

Allowable Claims and New Grounds of Claim Objection:

On page 1 of the Office Action, the examiner has allowed claims 35 and 48. The examiner has objected to claims 30, 33 and 50 as being dependent on a rejected claim. Without acquiescing in the objection or rejection of the base claims, applicants amend the base claims 24, 31, and 49 by incorporating the allowable subject matter of claims 30, 33, and 50, respectively, as indicated by the examiner. Consequently, applicants cancel claims 30, 33, and 50 without prejudice or disclaimer, which moots the claim objection.

New Grounds of Written Description Rejection:

On pages 3-6 of the Office Action, the examiner rejects claims 24-26, 29, 31, 34, 49 and 51-53 under 35 U.S.C. 112, first paragraph, allegedly for failing to comply with the written description requirement.

According to the examiner, the instant claims are drawn to methods of determining whether an individual is infected with *Neisseria gonorrhea* utilizing primers that facilitate amplification of a *porA* nucleic acid comprising residues 681-812 of SEQ ID NO:10; wherein said methods allow for the amplification of *Neisseria gonorrhea* *porA* nucleic acids but not *Neisseria meningitidis* (or any other *Neisseria*) *porA* nucleic acids (refers to claims 25-26 and 29); and the further use of oligonucleotide probes for detecting said amplified *porA* nucleic acids.

The examiner states that the specification discloses SEQ ID NO:1 and 2 that correspond to PCR primers specific for the *porA* gene of *Neisseria gonorrhoeae*. The examiner agrees that SEQ ID NO:1 and 2 meet the written description requirement, but contends that the number of primers encompassed by the instant claims is not small as the aforementioned claims are drawn to any and all PCR primers that hybridize to the residues 681-812 of SEQ ID NO:10, the *porA* gene of *Neisseria gonorrhoeae* but not *Neisseria meningitidis* (refers to claims 25 and 29) or any other *Neisseria* species (refers to claim 26).

The examiner also states that claims 31, 34, 49 and 51 required the use of oligonucleotide probes to detect the amplified *porA* product and the specification discloses SEQ ID NO:3 and 4 that correspond to oligonucleotide probes specific for specific for the *porA* gene of *Neisseria gonorrhoeae* but no other *Neisseria* species. The examiner agrees that SEQ ID NO:3 and 4 meet the written description provision of 35 USC 112, first paragraph, however contends that the number of primers encompassed by the instant claims is not small as the aforementioned claims are drawn to any and all oligonucleotide probes that hybridize to, a *porA* nucleic acid

(comprising residues 681-812 of SEQ ID NO:10) of *Neisseria gonorrhoeae* but not *Neisseria meningitidis* (refers to claims 25 and 29) or any other Neisserial species (refers to claim 26).

Applicants respectfully disagree with examiner and submit that one skilled in the art, based on the knowledge available in the field and the sequences disclosed in the instant specification, should be able to design primers and probes in order to practice the claimed methods. However, without acquiescing in the rejection, in order to expedite the allowance of the allowable claims, as indicated by the examiner, applicants amend claim 24 to recite "PCR primers comprising a nucleotide sequence selected from the group consisting of SEQ ID NO:1 and SEQ ID NO:2", which is the subject matter of dependent claim 30. Applicants also amend claims 31 and 49 to recite "wherein the probe comprises a nucleotide sequence selected from the group consisting of SEQ ID NO:3 and SEQ ID NO:4".

Regarding claim 51, applicants submit that the claim is amended to be dependent on currently amended claim 49, which is dependent on the allowed claim 48. Accordingly, written description requirement is fulfilled.

Regarding claims 52 and 53, applicants point out that the claims are dependent on the allowable claims 24 and 48, respectively, and do not recite primer or probe. Applicants also point out that claims 52 and 53 relate to a nucleotide sequencing step, which is well known in the art.

Applicants submit that support for sequencing of the amplification product can be found throughout the specification (see for example, paragraph [0074]). In this context, applicants request the examiner to consider the MPEP that states:

"...Information which is well known in the art need not be described in detail in the specification. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986)."

See MPEP §2163 II(A)2.02, Rev. 6, September 2007 at 2100-178.

In view of the above clarifications and amendments to the claims, applicants request withdrawal of the written description rejection.

REMARKS

Applicants submit that claims 24-26, 29, 31, 34-35, 48-49, and 52-53 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at 202- 434-1610 should there be any questions.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'John P. Isacson', is written over a horizontal line.

John P. Isacson
Reg. No. 33,715

March 4, 2011

Date

PERKINS COIE LLP
607 Fourteenth Street, NW
Washington, D.C. 20005-2003
Phone: 202.628.6600
Fax: 202.434.1690
Customer No. 90615